TÜVNORD

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

German Special Alloys GmbH
Carl-Friedrich-Benz-Straße 1b
47877 Willich
Germany

TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

medical@tuev-nord.de
tuev-nord-cert.com/en

TÜV®

Reference	Contact	Direct Dial	Date
No.: 44 235 151578	medical@tuev-nord.de	Tel.: +49 201 825 2236	16 September 2026

Notified Body Confirmation Letter

Reference: EC-Certificate acc. 93/42/EEC Annex V, No.: 44 235 151578

8003066434

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that TÜV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

German Special Alloys GmbH
Carl-Friedrich-Benz-Straße 1b
47877 Willich
Germany
SRN: DE-MF-000005088

TÜVNORD

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

TÜVNORD i. V. Digital unterschrieben von Mühlenberg Kevin Datum: 2026.09.16 15:28:51 +02'00'

i. V. Kevin Mühlenberg
Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. V. Digital unterschrieben von Hoy Benjamin Datum: 2026.09.16 15:27:30 +02'00'

i. V. Dr. Benjamin Hoy
TIC Manager MDR
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
GS-Alloy 1010 CB **++EGSAALMEKACOBSGZBD;** **++EGSAALMEKACOBSDRAL** **Trade name:** [redacted] **- realloy C** **-** [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1010 CB Blank **++EGSAALMEKACOBSFB9S** **Trade name:** [redacted] **- realloy C Blank**	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1010 CB Powder **++EGSAALMEKACOBSPUBW** **Trade name:** [redacted] **-** **- realloy C Powder** **-** [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1010 CB Softblank **++EGSAALMEKACOBSSBAZ** **Trade name:** **-** [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[redacted] - realloy C Softblank			
GS-Alloy 1010 CB Softblank R ++EGSAALMEKACOBSSBAZ Trade name: [redacted] - realloy C Softblank R - [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1020 CV ++EGSAALMEKACOBSGZBD; ++EGSAALMEKACOBSDRAL Trade name: [redacted] - realloy CH - [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1020 CV Blank ++EGSAALMEKACOBSFB9S Trade name: [redacted] - realloy CH Blank - [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1020 CV Powder ++EGSAALMEKACOBSPUBW Trade name: [redacted] -			

TÜVNORD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[redacted] - realloy CH Powder - realloy CH RPD [redacted] -			
GS-Alloy 1023 Classic ++EGSAALMEKACOBSGZBD; ++EGSAALMEKACOBSDRAL Trade name: [redacted] - realloy Classic [redacted] -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1023 Classic Blank ++EGSAALMEKACOBSFB9S Trade name: [redacted] - realloy Classic Blank	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1023 Classic Powder ++EGSAALMEKACOBSPUBW Trade name: [redacted] -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[redacted] - realloy Classic Powder [redacted] -			
GS-Alloy 1023 Classic Softblank ++EGSAALMEKACOBSSBAZ Trade name: - [redacted] - realloy Classic Softblank -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1023 Classic Softblank R ++EGSAALMEKACOBSSBAZ Trade name: [redacted] - realloy Classic Softblank R	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1025 GA ++EGSAALMEKACOBSGZBD; ++EGSAALMEKACOBSDRAL Trade name: [redacted] - realloy Ga280 -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1027 BCC ++EGSAALMEKACOBSGZBD; ++EGSAALMEKACOBSDRAL Trade name: [redacted] - realloy BC	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

TÜVNORD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- [redacted]			
GS-Alloy 1027 BCC Blank **++EGSAALMEKACOBSFB9S** **Trade name:** [redacted] **- realloy BC Blank** -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1027 BCC Powder **++EGSAALMEKACOBSPUBW** **Trade name:** [redacted] **- realloy BC Powder** -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1027 BCC Softblank **++EGSAALMEKACOBSSBAZ** **Trade name:** [redacted] **- realloy BC Softblank**	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1027 BCC Softblank R **++EGSAALMEKACOBSSBAZ** **Trade name:** - [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

TÜVNORD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[redacted] - realloy BC Softblank R			
GS-Alloy 1030 LA ++EGSAALMOGUCOBSGZST; ++EGSAALMOGUCOBSDRS2 Trade name: [redacted] -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1035 MG ++EGSAALMOGUCOBSGZST; ++EGSAALMOGUCOBSDRS2 Trade name: [redacted] - Modell FH	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1040 FH ++EGSAALMOGUCOBSGZST; ++EGSAALMOGUCOBSDRS2 Trade name: [redacted] - Modell EH [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

TÜVNORD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[redacted] -			
GS-Alloy 4080 LFC **++EGSAALMEKACOBSGZBD;** **++EGSAALMEKACOBSDRAL** **Trade name:** [redacted] **- realloy LFC**	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1055 BMS **++EGSALOTCOBSK9** **Trade name:** [redacted] **- realloy Universal Lot** [redacted] -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1056 Laserdraht **++EGSALASCOBSD8** **Trade name:** [redacted] - **- realloy Laserwire** - [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

TÜVNORD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
GS-Alloy 5010 N+ **++EGSAALMEKANIBSGUDG** **Trade name:** [redacted] **- realloy N+** - [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 5010 N+ Blank **++EGSAALMEKANIBSFBC7** **Trade name:** [redacted] **- realloy N+ Blank**	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 5010 N+ Powder **++EGSAALMEKANIBSPUEB** **Trade name:** [redacted] **- realloy N+ Powder**			
GS-Alloy 5011 Easy **++EGSAALMEKANIBSGUDG** **Trade name:** [redacted] - [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 5012 N **++EGSAALMEKANIBSGUDG** **Trade name:** [redacted] - [redacted]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

TÜVNORD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[redacted] - realloy N [redacted] -			
GS-Alloy 5013 M11 ++EGSAALMEKANIBSGUDG Trade name: [redacted] -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 5015 Base ++EGSAALGUFEBSGUSU Trade name: [redacted] - realloy Base	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

TÜVNORD

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/05	Rev00	Initial issue
2024/02/06	Rev01	Adding trade names, according to P111F007_Produktliste_GSA_rev00
2024/05/07	Rev02	Adding trade names, according to P111F007_Produktliste_GSA_rev01
2025/03/17	Rev03	Adding trade names, according to P111-F-007 Produktliste GSA Rev.03 2025-03-13
2026/03/18	Rev04	Adding and deleting trade names, according to P111-F-007 Produktliste GSA 2025-10-30
2026/09/16	Rev05	Adding and deleting trade names, according to P111-F-007 Produktliste GSA 2026-08-17